IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 0 1 2006

Application of:

TAKAHARA HAMADA

Ser. No.: 10/786,321

Filed: 2/25/04

SAFETY TEST SUPPORT SYSTEM, METHOD AND PROGRAM

Group Art Unit: 1631

Examiner: Mary Zeman

RESPONSE TO REQUEST FOR INFORMATION

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This paper and the accompanying PTO Form-1449 are being submitted in response to the Request for Information dated August 28, 2006. This Response will reference the individual documents referring to the citation letters included on the PTO Form-1449.

A prior art search was performed whereby Documents A and B were discovered. Applicants relied upon Documents C and D to develop the present invention. The names of any products or services that have incorporated subject matter related to the claimed invention are outlined in Document E. A publication which one of the Applicants authored and which describes the disclosed subject matter is provided as Document F. Documents which were used as sources for the description of the prior art include Documents G-I.

> 37 CFR 1.8 CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 10-30-06 (date).

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Document A is related to safety-test evaluation systems. The system disclosed in this reference indicates the data modification log when necessary and includes a data record. The data record consists of one sequence of records that includes the modified study record, which is stored into the modification data file each time the study record is changed. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

Document B relates to program tests. However, multiple test results are kept as a test result log. The system then extracts the difference by comparing the two time separated test results. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

Document C relates to safety-test evaluation systems. This system stores validation procedures and the results. The system runs the stored validation procedure automatically and compares the result with the result of a previously stored result already in the system. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting

changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

Document D relates to safety-test evaluation systems. This system only displays the registered program list and allows a selected program to be operated. This document fails to disclose "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

A specific improvement of claim 1 over the cited art includes "second program storage for storing check programs each for detecting a change in one of the application programs during the system operation; and an inspection conducting means for detecting changes in the application programs by sequentially executing the stored check programs in response to an inspection conducting signal."

A specific improvement of claim 2 over the cited art includes the capability that "if a change that does not affect the system operation is detected in one of the application programs during the system operation, the associated check program ignores the change, and wherein, if a change that affects the system operation is detected in one of the application programs during the system operation, the associated check program regards the change as a change."

A specific improvement of claim 3 over the cited art includes "the inspection conducting means inspects the application programs by: identifying the application program associated with each of the check programs; inputting a

pseudo-signal directly to the identified application program; detecting a response signal responsive to the input pseudo-signal; and comparing the detected response signal with a response signal detected before the inspection."

A specific improvement of claim 4 over the cited art includes that "the pseudo-signal is input without passing through an operation system."

A specific improvement of claim 5 over the cited art includes that "the pseudo-signal is input through an operation system."

Claims 6 and 7 also contain additional differences over the cited art.

Claim 8 is a method claim similar to claim 1 and therefore contains similar improvements over the cited art. Claim 9 is another method claim similar to claim 1 and therefore contains similar improvements over the cited art.

Should any additional information be required, Applicants' undersigned attorney will provide the requested details.

Respectfully submitted,

John S. Mortimer, Reg. No. 30,407

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Date: 0 ct 30 2006

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INFORMATION DISCLO\$URE 💆							First Named Inventor		TAKAHARU HAMADA		
STATEMENT BY APPLICANT						۶	Group Art Unit		1631		
(Use as many sheets as necessary)							Examiner Name		Mary Zeman		
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				FORE	EIGN PA	TEN	T DOCUMENTS	5			
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Substitute for form 1449A/PTO				Application Number	10/786,321		
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) Sheet 2 of 2		Filing Date	2/25/04			
STATEMENT BY APPLICANT				First Named Inventor	TAKAHARU HAMADA 1631		
				Group Art Unit			
(Use as many she	ets as nece	ssary)		Examiner Name	Mary Zeman		
Sheet	2	of	2	Attorney Docket No.	MUR-01460P00030US		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²						
	E	TOX LAUNCHER - Advertisement/Information Sheet							
	F	Functions and Developments of TOX-LAUNCHER - Author: Takaharu Hamada - Updated February 2005 21 CFR Part 58							
	G								
	H Guidance for Industry - Part 11, Electronic Records; Electronic Signatures - Scope and Application - August 2003 Pharmaceutical CGMPs								
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